

K972356

**510(K) SUMMARY**

AUG 26 1997

**1. SUBMITTER:**

Innovasive Devices, Inc.  
734 Forest St.  
Marlborough, MA 01752  
Telephone: 508-460-8229

Contact: Stephen M. Page, Manager of Regulatory Affairs  
Date Prepared: June 20, 1997

**2. DEVICE:**

Innovasive 2.3mm ROC EZ Suture Bone Fastener  
Classification Name: Single/multiple component bone fixation appliances and accessories.  
Trade Name: Innovasive Devices ROC EZ Suture Bone Fastener

**3. PREDICATE DEVICES:**

The predicate devices used to determine substantial equivalence for the modified Innovasive Devices 2.3mm ROC EZ Suture Bone Fastener were:

- a. The 2.8mm/3.5mm Innovasive Devices ROC EZ Suture Bone Fastener, marketed by Innovasive Devices, Marlborough, MA,
- b. The 1.9mm/2.3mm Innovasive Devices ROC Suture Bone Fastener marketed by Innovasive Devices, Marlborough, MA, and
- c. The 1.8mm Mitek Mini Anchor marketed by Mitek Products, 60 Glacier Drive, Westwood, MA.

**4. DEVICE DESCRIPTION:**

The ROC EZ suture bone fastener implant tip portion consists of a shear pin, expander and sleeve. The expander and sleeve is fitted onto the shear pin component such that the expander component is located below the sleeve on the shear pin. As the shear pin is pulled up during the device deployment, the expander engages the sleeve. The expander is tapered such that it will fit into the sleeve component as the deployment action progresses. As the expander is drawn into the sleeve, the sleeve expands to make contact with the surrounding bone. This expanding sleeve results in the final fixation properties of the device. Once the expander is completely seated inside the sleeve, the shearing pin shears from the fastener assembly resulting in the device being fixated into the bone hole.

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In addition to the Fastener, a stainless steel drill and drill guide is available to establish the proper hole in the bone for the Fastener along with an obturator, deployment handle and hole finder. All of the instrumentation except the Fastener will be offered as reusable devices and can be autoclaved in the sterilization tray provided for this purpose.

The Fastener will be available as a sterile, single use device in both an open and arthroscopic version. Both sutured and sutureless versions will be marketed.

## **5. INTENDED USE:**

The 2.3mm ROC EZ Suture Bone Fasteners are intended for the reattachment of soft tissue to bone for the following indications:

### **ANKLE**

1. Lateral instability
2. Medial instability
3. Achilles tendon reconstruction and repair
4. Mid-foot reconstructions

### **HAND**

1. Ulnar or lateral collateral ligament reconstruction

### **WRIST**

1. Scapholunate ligament reconstruction

### **FOOT**

1. Hallux valgus reconstruction

### **ELBOW**

1. Tennis elbow repair
2. Biceps tendon reattachment
3. Medial and lateral repairs

## **6. COMPARISON OF CHARACTERISTICS:**

The existing Innovasive Devices 2.8mm/3.5mm ROC EZ Suture Bone Fastener is comprised of two polymer components, high density polyethylene and acetyl plastic. This device is used to secure a suture in a predrilled hole in bone. It remains fixed in the bone through radial compression as the device is deployed. This remains true for all sizes of the device.

The 2.3mm ROC EZ device incorporates the same design and materials as the existing 2.8mm/3.5mm ROC EZ. The only difference is the size. As with the predicate device, the 2.3mm ROC EZ uses an expander fitted on a shear pin which is drawn up into an expandable sleeve. The sleeve expands as the expander is drawn up into it. The shear pin then shears resulting in the device being fixed into the bone site.

## **7. PERFORMANCE DATA:**

The following performance data was provided in support of the substantial equivalence determination:

1. Bone model testing: Comparison of the ultimate holding strength in a bone model compared to the predicate devices. The Innovasive 2.3mm ROC EZ Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate devices.
2. Cadaver testing: Comparison of the ultimate holding strength in cadaver compared to the predicate device. Again, the Innovasive 2.3mm ROC EZ Suture Bone Fastener holding strength was found to be equivalent to the strength of the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Stephen M. Page  
Manager of Regulatory Affairs  
Innovasive Devices, Inc.  
734 Forest Street  
Marlborough, Massachusetts 01752

AUG 26 1997

Re: K972356  
Innovasive 2.3mm ROC™ EZ Suture Bone Fastener  
Regulatory Class: II  
Product Code: MBI  
Dated: June 20, 1997  
Received: June 25, 1997

Dear Mr. Page:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

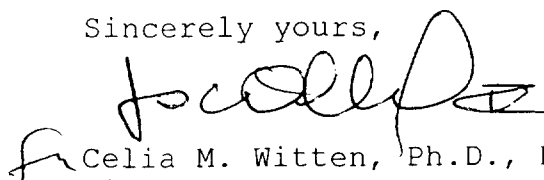
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**INDICATIONS FOR USE****ANKLE**

Lateral instability  
Medial instability  
Achilles tendon reconstruction and repair  
Midfoot reconstructions

**HAND**

Ulnar or lateral collateral ligament reconstruction

**WRIST**

Scapholunate ligament reconstruction

**FOOT**

Hallux valgus reconstruction

**ELBOW**

Tennis elbow repair  
Biceps tendon reattachment  
Medial and lateral repairs

Prescription Use X  
(Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K972356